FEB 2 8 2014

K133609

Page 1 of 3

NDS
SURGICAL · IMAGING

510(K) SUMMARY

A. Manufacturer:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
B. Submitted By:	Jim Leng Regulatory Engineer/NDS Surgical Imaging, LLC
B1, Address:	NDS Surgical Imaging, LLC 5750 Hellyer Avenue San Jose, CA 95138 USA
C. Date of Preparation:	November 15, 2013 Revision: January 29, 2014 Revision: February 20, 2014
D. Contact Information:	Tel: 408-776-0085 Fax: 408-776-9878
E. Classification:	Picture Archiving Communication System
F. Common Name:	System, Image Processing, Radiological
G. Proprietary Name:	The Dome® S6c monitor
H. Classification Number:	21 CFR 892.2050
I Product Code:	LLZ
J. Substantial Equivalence:	Dome model S6c is substantial equivalent to the predicate device K032638 Dome model C3 color. Both devices have the same indication for use with the same characteristics. Dome model S6c series is a 6MP display device, equivalent to the resolution of dual 3MP radiology displays. Both devices have the same viewing angle, number of colors and utilize the same backlight stabilization and calibration technologies. The physical size difference does not impact display information and viewing.
K. Device Description:	The Dome model S6c is a widescreen 30–inch 6 megapixel color monitor. Its sleek design, high brightness and bezel free separation between two 3MP displays makes Dome model S6c ideal for read of patient images acquired from multiple medical imaging modalities.

NDS
SURGICAL · IMAGING

L. Intended Use: The Dome Sx line, model S6c is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

Model Dome S6c is not intended for mammography use.

M. Technological Characteristics: Bezel-free framing of 6 megapixels of data is presented in a 30 inch diagonal display landscape format with resolution of 3280 x 2048 and a pixel pitch of 0.197mm. The integrated Dome RightLight Controller monitors and stabilizes backlight luminance. The display unit includes a PCI Express graphics board to support the required dual-link connectivity for the display.

Characteristic Items	**Predicate device K032638**	**Specification K 133609**
Intended Use	The DOME CX ™DIGITAL FLAT-PANEL DISPLAY SYSTEM™, Model C3 Color™ and C3 Gray are intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.	Dome Sx line, model Dome S6c is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.
Screen		
Screen diagonal	20.8" Diagonal (528 mm)	30" Diagonal (762 mm)
Resolution	1536 x 2048 pixels (portrait) 2048 x 1536 pixels (landscape)	Dual 1536 x 2048 pixels (portrait) (Note: future implementation) Dual 1640 x 2048 pixels (portrait) 3280 x 2048 pixels (landscape)
Pixel pitch	0.207 mm	0.197 mm
Contrast ratio	600:1 – typical	1000:1 – typical
Brightness	235 cd/m² typical	800 cd/m² typical
Pixel rise/fall time	50 ms	30 ms typical
Viewing angle (CR 10:1)	+/- 85° (170°) horizontal +/- 85° (170°) vertical	+/- 85° (170°) horizontal +/- 85° (170°) vertical
Viewing Characteristics		
Stabilization, calibration, and automated QA	Built in RightLight rear sensor for backlight stabilization. Factory calibrated. QA through manual external photometer	Built in RightLight rear sensor for backlight stabilization. Factory calibrated. QA through embedded RightCheck front sensor and manual external photometer
Characteristics		
Look up table	10/12 bit	10/12 bit

NDS
SURGICAL IMAGING

Interface		
Digital Video Input	1x DVI Revision 1.0 single channel connector	1x DVI Revision 1.0 digital dual-channel connector
Input Formats		
Landscape Orientation	2048x1536 (8 bits per pixel, 24 bit color)	3280x2048 (8 or 10 bit per pixel, 24 bit or 30 bit color)
Portrait Orientation	1536x2048 (8 bits per pixel, 24 bit color)	2x 1536x2560 or 2x 1640x2048 (8 or 10 bit per pixel, 24 bit or 30 bit color)
Power Requirements		
Power Supply	100 ~ 240 VAC 50~60Hz	100 ~ 240 VAC 50~60Hz Universal Auto Switching with Medical Approvals and PFC
Regulatory Approvals		
Safety	EN 60601-1 Part 1. General requirements for safety	IEC 60601-1: 2005
EMI	EN 55011 Class B	EN 60601-1-2: 2007

N. Conclusion:

Based upon our test results, the Dome model S6c radiology display meets IEC/EN60601-1 and 60601-1-2 standards which establish its safe design and operation. The Dome model S6c and the predicate device model C3 color are identical in terms of indication for use, characteristics, specifications and performance. The difference is Dome model S6c is one package that replaces two Dome model C3 color side by side displays in use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2014

NDS Surgical Imaging, LLC
% Mr. Jim Leng
Regulatory Engineer
5750 Hellyer Avenue
SAN JOSE CA 95138

Re: K133609
Trade/Device Name: The Dome® S6c
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 5, 2014
Received: February 6, 2014

Dear Mr. Leng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133609

Device Name
The Dome S6c Color Monitor

Indications for Use *(Describe)*

Dome Sx line, model Dome S6c is intended to be used in displaying and viewing medical images for review and analysis by trained medical practitioners.

Model Dome S6c is not intended for mammography use.

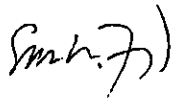
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."